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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/871,318
Filing Date: May 31, 2001
Appellant(s): FIKSTAD ET AL.

Malcolm McGowan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/23/07 appealing from the Office action mailed 12/07/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

This appeal involves claims 3-5,14,17-19,22-40. Claims 1,2,6-13,15,16 and 18-21 have been canceled. Due to a typographical error claim 40 was not rejected. The subject matter of claim 40 has clearly been rejected in the previous Office Actions. It is the position of the Examiner that the claims would have been rejected in any of the previous Office Actions, and is rejected now.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,203,817	CORMIER et al	03-2001
6,323,232	KE et al	11-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-5,14,17-19, and 22-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Cormier et al (USPN 6,203,817 hereafter '817) in view of Ke et al (USPN 6,323,232 hereafter '232). The claims are drawn to a transdermal formulation comprising an adhesive drug matrix reservoir and lasofoxifene.

The '817 patent discloses a transdermal formulation comprising an adhesive matrix reservoir (abstract). The transdermal attached to the skin and comprises an adhesive overlay

(part 22), a backing layer attached to the overlay (part 14), a reservoir under said backing layer (part 12), an optional active agent-permeable layer under said reservoir, a further disc layer (part 24), and a release liner (not pictured) (column 9, line 21-60). The device is further sealed to prevent leakage (column 9, line 30-35). The transdermal device further comprises permeation enhancers such as ethanol or propylene glycol (column 10, lines 5-29; examples). The transdermal comprises a gel matrix comprising gelling agents such as hydroxypropylcellulose and colloidal silicone dioxide (column 10, lines 22-39). The transdermal formulation delivers various active agents including antiestrogen and antiosteoporotic agents such as tamoxifen and raloxifene (column 7, lines 66-68; column 8, lines 9-12). The reference however lacks a disclosure of lasofoxifene, a similar antiestrogen agent.

The '232 patent discloses a combination f active agents in a transdermal comprising including lasofoxifene and other estrogen agonists/antagonist (claim 1). Among other agents used in the combination therapy are droloxifene, raloxifene and tamoxifen (column 6, lines 35-40). The transdermal formulation comprises propylene glycol and is sterile (column 37, lines 38-52). These agents are identical to those preferred in the '817 patent and act as functional equivalents of each other. It would have been obvious to include the lasofoxifene of the '232 patent into the device of the '817 patent since they comprise similar components, and are within the same field of endeavor.

With these things in mind one of ordinary skill in the art would have been motivated to combine the lasofoxifene of the '232 patent in to the device of the '817 patent in order to provide an improved antiosteoporotic effect to the device. The artisan would have been able to combine the components since they comprise similar carriers, and permeation enhancers. It would have

been obvious to make the simple substitution and combination with an expected result of a viable transdermal device useful in treating various estrogen related disorders.

(10) Response to Argument

Applicant argues that:

1. The combination of the '817 and '232 patents does not teach or disclose a transdermal formulation as recited in the claims.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the arguments specifically, it remains the position of the Examiner that the combination of the '817 and '232 patents discloses each and every limitation of the claims either explicitly or inherently, rendering the claimed invention obvious. The '817 patent discloses a transdermal device comprising an adhesive overlay, backing layer, and active agent permeable layer with a reservoir disposed between them. The device is sealed to prevent leakage and further includes a further layer as a protective disk (part 24) along with a release liner. The reference discloses a wide range of active agents including raloxifene (column 8, lin. 10). This establishes the level of skill in the art regarding selective estrogen receptor modulators (SERMs). This establishes a level of success regarding their presence and effectiveness in transdermal formulations. It is the position of the Examiner the inclusion of a different SERM into a similar carrier device would be well within the level of skill in the art. Despite the different chemical structures of each drug, their presence as functional equivalent would render any substation

obvious. The raloxifene of the '817 patent is the same raloxifene of the '232 patent that is used as a functional equivalent of the lasofoxifene of the '232 patent. The artisan of ordinary skill is well aware of the difference in chemical structure and the changes that must be made to a matrix during formulation in order to achieve proper delivery. These changes and modification are merely routine experimentation. Each compound is used for the same purpose of addressing an estrogen related disorder as an antagonist/agonists. Knowing their relationship, it would have been obvious to make the substitution in order to achieve the desired treatment method. The '232 reference provides several SERM compounds all with separate and distinct structures yet each applied to a successful transdermal formulation. It is well within the level if skill in the art to optimize a device's carrier and matrix components dependent on the drug, this is seen in both the '232 and '817 patents. This is the definition of routine experimentation.

Regarding the differing transdermal formulation, it remains the position of the Examiner that the combination of the '817 and '232 patent renders the claims obvious. Applicant argues that since the '232 patent discloses a solution or suspension and the '817 patent discloses a gel formulation there is no reason to combine them. Applicant is reminded that the '232 patent is merely relied upon for it's disclosures of lasofoxifene in transdermal formulation comprising propylene glycol, ethanol, glycerin and other emulsifiers common in the art and shared by the '817 patent. The '232 patent discloses that the formulation can be a solution, suspension or emulsion comprising components identical to some disclosed in the '817 patent. The reference establishes the level skill in the art regarding the delivery of lasofoxifene, ralofoxifne in combination with ethanol, propylene glycol and emulsifiers, the same compo0unds present in the transdermal delivery device of the '817 patent. It would have been obvious to combine the

compounds of the '232 patent in to the device of the '817 patent with an expected result of a transdermal delivery device useful in treating estrogen related disorders.

Regarding the peel seal disc, it remains the position of the Examiner that the lowered pictured layer of the '817 patent (part 24) would act as a protective peel seal disk in the transdermal device.

Regarding the heat seal limitation it is the position of the Examiner that such a limitation is merely a product-by-process limitation bearing little patentable weight. Applicant is reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The purpose of the seal is to prevent leaks and maintain the integrity of the transdermal device. Whether the seal is delivered via a heat source or some other source is irrelevant when the end result is a sealed and stable transdermal delivery device. It is the position of the Examiner that such a limitation does not impart patentability to the claims in view of the sealed transdermal device of the '817 patent.

Regarding the methods of claim 17 and 32 it is the position of the Examiner that these methods are disclosed in the prior art. The '817 patent discloses a method of delivering a wide variety of active agents including SERMs. The '232 patent discloses methods of treating various estrogen related disorders with SERMs such as lasofoxifene and other SERMs disclosed in the '817 patent. The active step of the claimed method is merely administration of a formulation

comprising lasofoxifene. This is met by the '232 patent. The species device is met by the '817 patent that teaches delivery of similarly functioning compounds. It would have been obvious to combine the methods and lasofoxifene of the '232 patent in to the device of the '817 in order to provide a stable delivery device to treat a wide variety of estrogen related disclosers including osteoporosis.

Regarding the permeation enhancers recited in the claims, it is the position of the Examiner that such cell-envelope disrupting compounds are disclosed in the '817 patent and obviate the claims. Propylene glycol is a well-known permeation enhancer and is disclosed in the prior art as useful in the invention. Applicant is directed to the examples of the '817 patent where propylene glycol is prominently featured. Likewise regarding the gel forming polymers. For these reasons at least the claims remain obviated.

Regarding hydroalcohol gel recited in claim 32, it is the position of the Examiner that the prior art discloses such a transdermal formulation. The '817 patent discloses a transdermal gel comprising cellulose ethers, alcohols and gelling agents. Applicant's attention is directed to column 10, lines 22-39 of the '817 patent where the gelling components are disclosed. These disclosures taken with the lasofoxifene would render the claims obvious.

In conclusion it remains the position of the Examiner that one of ordinary skill in the art would have found it obvious to substitute the equally well known lasofoxifene of the '232 patent into the device of the '817 patent in order to achieve the predictable result of a transdermal device useful in treating osteoporosis. For these reasons the claims remain rejected.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

MP Young

Conferees:

Michael Hartley

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